

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  91641	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International application No.  PCT/AU99/00306	International filing date (day/month/year)  23 April 1999	Priority Date (day/month/year)  23 April 1998	
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>7</sup> C12Q 1/68, 1/48; C12N 15/54			
<b>Applicant</b> COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION et al			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 52 sheet(s).

3. This report contains indications relating to the following items:

I	<input checked="" type="checkbox"/> Basis of the report
II	<input type="checkbox"/> Priority
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/> Lack of unity of invention
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/> Certain documents cited
VII	<input type="checkbox"/> Certain defects in the international application
VIII	<input type="checkbox"/> Certain observations on the international application

Date of submission of the demand  11 November 1999	Date of completion of the report  4 July 2000
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>JULIE CAIRNDUFF</b> Telephone No. (02) 6283 2545

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

the international application as originally filed.

the description, pages 1 to 4, 12 to 44, as originally filed,  
pages , filed with the demand,  
pages 5 to 11, received on 26 June 2000 with the letter of 26 June 2000

the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages 62 to 72, received on 26 June 2000 with the letter of 26 June 2000

the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages 1/17 to 17/17, received on 30 June 1999 with the letter of 30 June 1999

the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages 1/17 to 17/17, received on 30 June 1999 with the letter of 30 June 1999

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4.  The amendments have resulted in the cancellation of:

the description, pages 45-61

the claims, Nos.

the drawings, sheets/fig.

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-50	YES
	Claims	NO
Inventive step (IS)	Claims 1-50	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-50	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

**Citations**

- D1: AU 31341/95 (THE JOHN HOPKINS UNIVERSITY SCHOOL OF MEDICINE) 1 February 1991
- D2: Lee, W.H. et al. (1997) Cancer Epidemiology, Biomarkers and Prevention, volume 6, pp. 443-450
- D3: Jhaveri, M.S. et al. (27 March 1998) Gene, volume 210, number 1, pp. 1-7
- D4: Lee W.H. et al. (1994) Proceedings of the National Academy of Sciences USA, volume 91, pp. 11733-11737
- D5: Frommer M. et al. (1992) Proceedings of the National Academy of Sciences USA, volume 89, number 5, pp. 1827-1831

**Novelty and Inventive Step**

Claims 1 to 50 are considered novel and inventive when compared to any one of D1 to D5. None of the citations disclose a method to identify abnormal methylation of cytosine within the glutathione-S-transferase (GST) Pi gene or its regulatory flanking sequences defined by (and inclusive of) CpG sites -43 to +55, using a selective amplification technique. Furthermore none of D1 to D5 identify specific sequences that may be used in the exemplified method. As a result claims 1 to 50 are novel and inventive.

**Industrial Applicability**

Claims 1 to 46 exhibit industrial applicability.